



ROYAL NORWEGIAN MINISTRY
OF THE ENVIRONMENT

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Effective regulation of nanomaterials – comments by Norway

Norway pursues an ambitious chemicals policy, both nationally and internationally, to promote a high level of protection for human health and the environment. There is a need for urgent action on regulating the manufacturing and use of nanomaterials and nanomaterials in products. The basic goal in the Norwegian strategy for nanomaterials is to achieve the same level of protection for human health and the environment from potential risks of nanomaterials as for other chemicals. The regulatory regime has to be improved in order to safeguard health and environment. Current lack of knowledge on risks represents a challenge to be addressed in the work to improve regulations.

Norway has the same legislation in the chemicals and waste area as the EU through the EEA Agreement. Norway believes that REACH, which is established as the basic regulation of chemicals, could be utilized to protect health and environment from possible risks from nanomaterials. So far, however, REACH and other legislation are not equipped to deal with the specificities of nanomaterials. Existing tonnage thresholds for registration in REACH exceed the quantities in which most nanomaterials enter the European market, creating a possible loophole to be sealed. The data requirements for registration of chemicals in REACH does not include nanospecific characteristics, and risk assessment and exposure tools are not applicable to nanomaterials. Consequently, the regulation does not sufficiently address possible risks to health and environment from nanomaterials, and the possibility to restrict the production and use where necessary is at the moment limited.

We welcome the recommendation from the European Commission of 18 October 2011 on the definition of nanomaterial, and believe that this definition should be used in the

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work to improve the regulation of nanomaterials.

In our opinion, the following elements have to be improved to make legislation work:

- The legislation should ensure chemical safety assessment for all nanomaterials including exposure scenarios and safety assessment
- The registration of nanoforms of substances should be mandatory. Information on coated nanomaterials should be included in the registration
- The production/import threshold for registration of nanomaterials should be considerably lower than the current threshold in REACH (irrespective of uses), and registration deadlines should be established for nanomaterials independently of the phase in deadline for the bulk form of a chemical
- The legislation should include specific data requirements for nanomaterials as the nanosubstance identity may not be fully characterized by chemical composition. Such specific data requirements may include surface area, form, reactive surface, grain size distribution and optical properties.
- Test methods and guidelines should be adjusted, and risk assessment and exposure tools improved, in order to make them applicable to assess health and environment risks from nanomaterials

These elements could be improved by developing a new legislation, by modifying REACH, its annexes and TGDs, or by adding a “nano-patch” on REACH, i.e. a stand-alone legislation for registration of nanosubstances parallel and linked to REACH and that might also address specific product groups. Norway believes it would be beneficial to avoid starting a time-consuming process to develop a wholly new legislation. Instead, we believe REACH should be utilized. The possibility to add a “nano-patch” to the regulation would specify how REACH tools and provisions should be applied with respect to nanomaterials. Relevant annexes and guidance of REACH should also be amended where this is necessary to achieve a regulatory regime that efficiently provides the same level of protection for human health and the environment as for other substances.

Yours sincerely,



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